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TEST REPORT

FLUID INFUSION SYSTEM

(NASA-CR-141565) FLUID INFUSION SYSTEM (Beckman Instruments, Inc., Anaheim, Calif.) 15 p HC $3.25 CSCL 20D

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1.0 INTRODUCTION

This report describes and summarizes performance testing carried out in the development of the prototype zero-g fluid infusion system under NASA-JSC Contract NAS9-14080. Engineering tests were performed in the course of development, both on the original breadboard device and on the prototype system. This testing was aimed at establishing baseline system performance parameters and facilitating improvements. Acceptance testing was then performed on the prototype system to verify functional performance. Acceptance testing included a demonstration of the fluid infusion system on a laboratory animal.

2.0 ENGINEERING TESTING

The procedures followed and the results obtained in engineering tests are described in sections 2.1 through 2.3.

2.1 Flow Tests

2.1.1 Breadboard Flow Tests

The most important system performance parameter is accuracy of flow regulation. Early in the program, tests were made to establish the flow characteristics produced by the currently most widely used technique--declining hydrostatic head--and the ideal situation of constant fluid pressure applied uniformly over the entire bag exterior. A pressure infusor currently available off the shelf was also tested.

The technique used for measuring flow rate was simply timing the delivery into a graduated cylinder. The volume increment used for this purpose was 5 ml for low flow rates (5 ml/min. nominal), and 50 ml for higher flow rates (50 to 100 ml/min. nominal). Experimental accuracy inherent in this method is on the order of 2 to 3 percent.

Results of the early investigations are shown in Figures 1 and 2. The measured flow rates (Figure 1) and the measured liquid pressure (Figure 2) in the bags are shown as functions of the cumulative liquid volume expressed from the bag. Figure 1 shows two useful baselines. Curve (1) represents a practical ideal--flow is constant except for secondary effects due to elasticity of the fluid bag walls. Curve (2) represents the results obtained in current every-day practice, and shows the substantial decline in flow rate that occurs as the contents of a fluid bag are delivered. Figure 2 shows the flow curves obtained from two devices: the hand-pumped Fenwal pressure infusor, and the original Beckman breadboard fluid infusion system. A factor common to both was the fact that the pneumatic pressure in the device was held constant and it was assumed that this would result in constant liquid pressure. The curves show that this was not the case, however. The Fenwal device did a better job of producing constant flow because of the more conformal nature of the device-to-fluid bag interface. Contact area between bag and pressure plate in the original breadboard was highly variable, and this resulted in a severe decline in flow. Discovery of this effect led to a new conceptual design that was embodied in the prototype fluid infusion system.

2.1.2 Prototype Flow Testing

The superior pneumatic design adopted for the prototype system avoided the gross flow rate errors noted previously. Large flow anomalies were sometimes noted in the prototype engineering tests; however, these were associated with failure modes rather than inherent deficiencies of the design, and they were eliminated. One effect that was found to be systematic, however, was a slow decay in flow at the lower flow rates. This is believed due to elasticity and dimensional stability effects in the flexible tubing. No other consistent effects were noted, and it was found possible to produce a constant flow within ±8% at the lower flow rates and ±5% at the higher flow rates. Some representative flow curves obtained in engineering tests of the prototype system are shown in Figures 3 and 4.

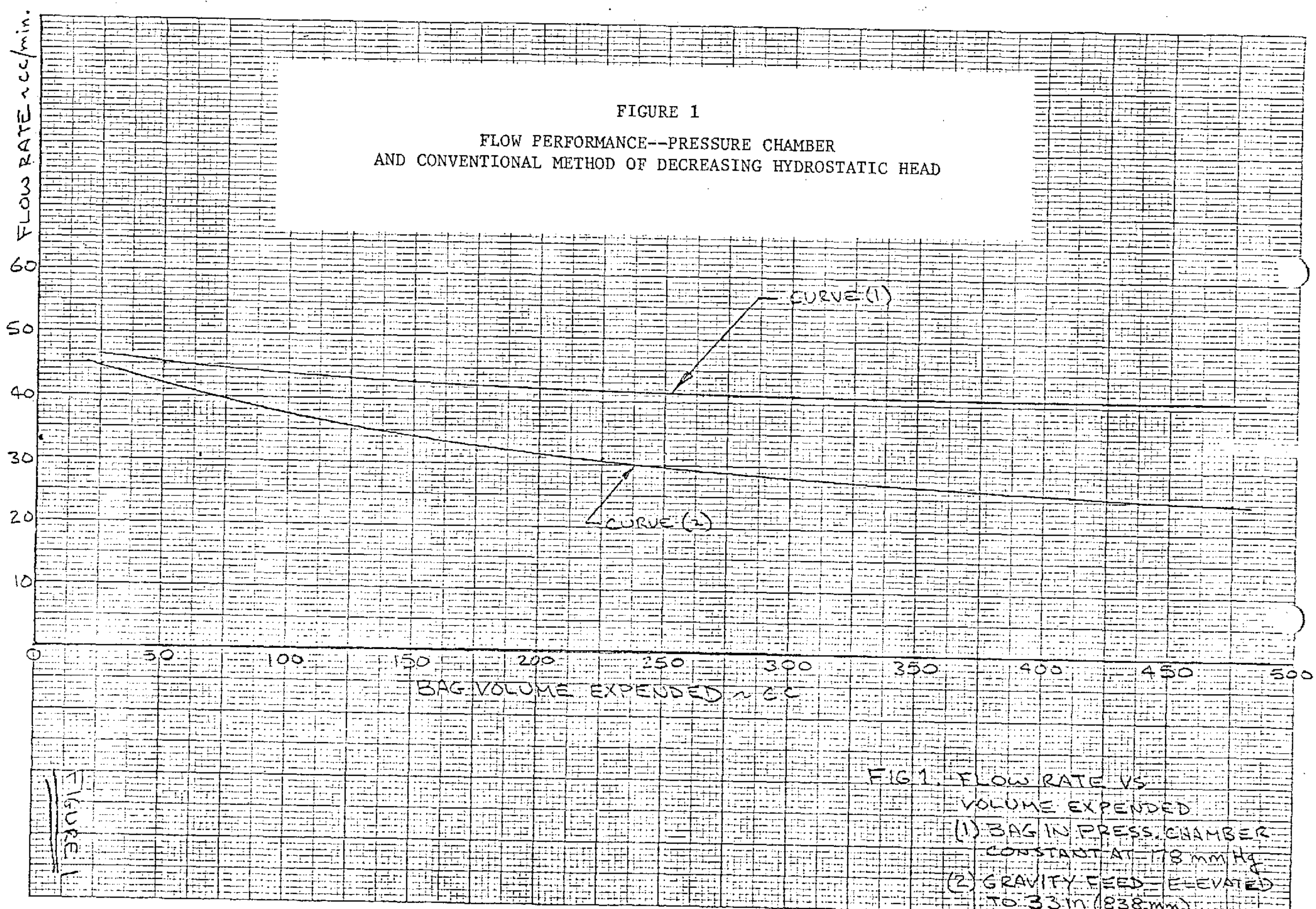

FIGURE 1

FLOW PERFORMANCE--PRESSURE CHAMBER AND CONVENTIONAL METHOD OF DECREASING HYDROSTATIC HEAD

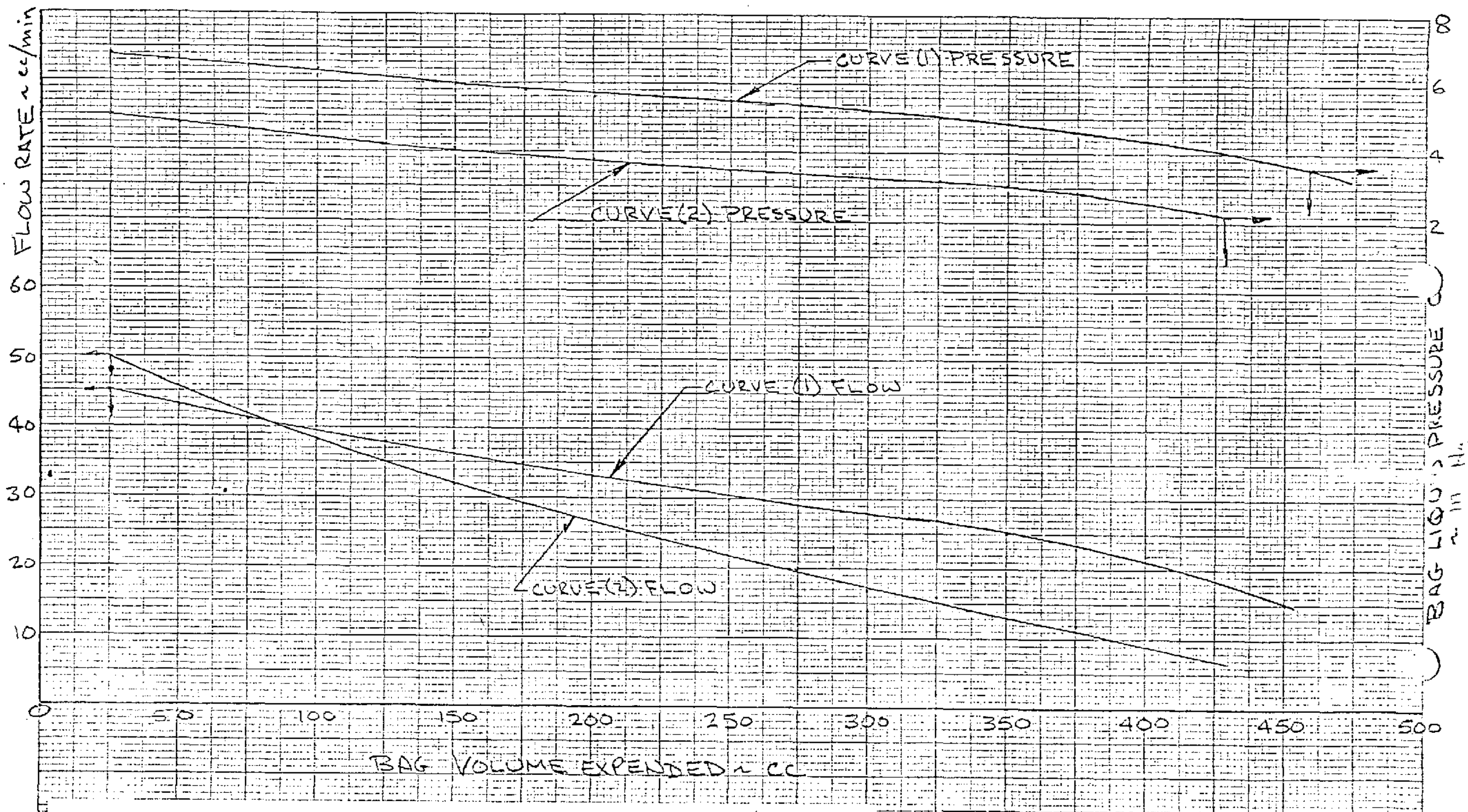

FIGURE 2

FLOW PERFORMANCE--COMMERCIAL PRESSURE INFUSOR AND INITIAL BECKMAN ATO BREADBOARD DESIGN

K+E 10 X 10 TO 1/2 INCH 46 1323
7 X 10 INCHES MADE IN U.S.A.
KEUFFEL & ESSER CO.

IVI FLOW TESTING

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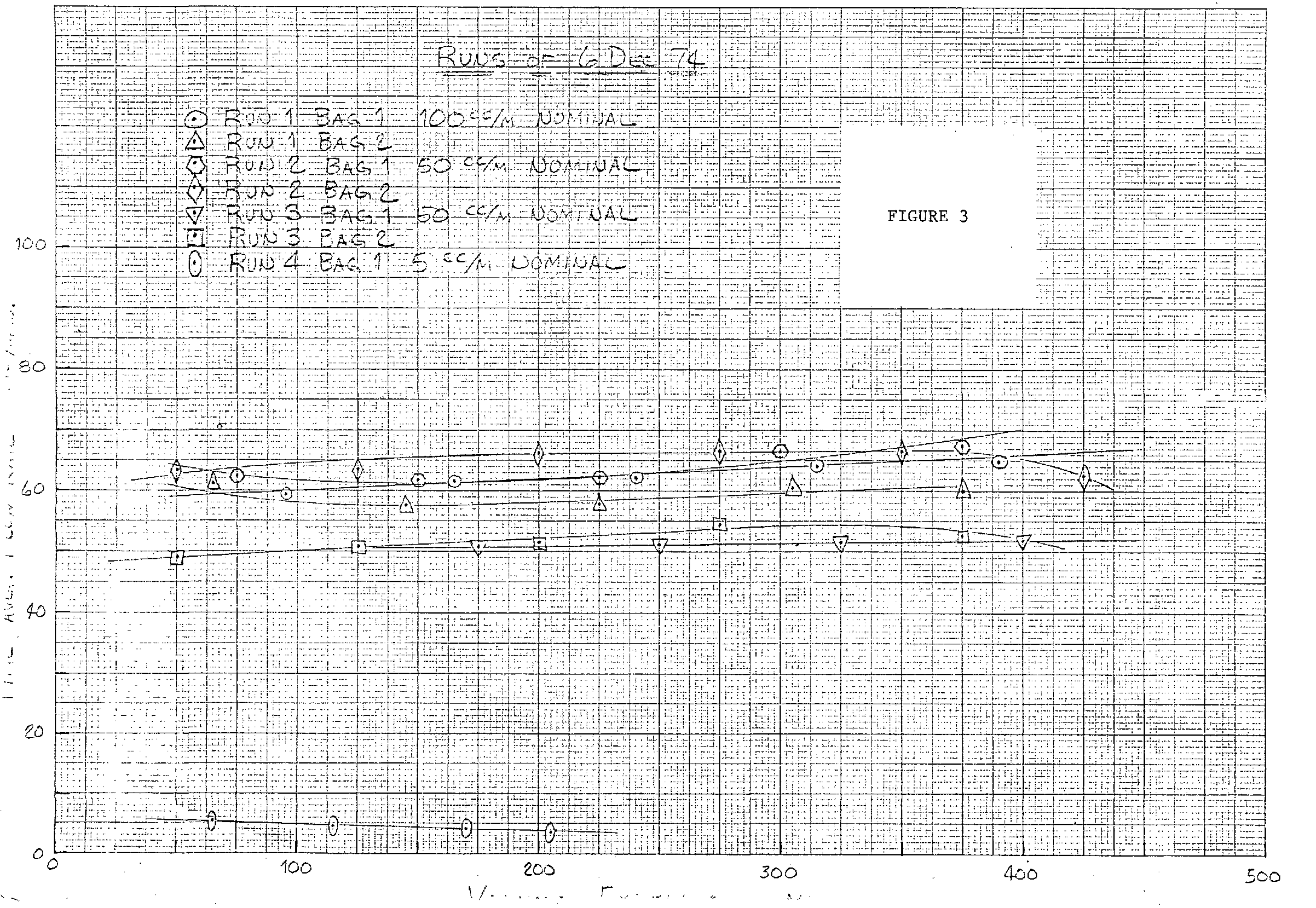

FIGURE 3

IVI FLOW TESTING - 13 DEC 74

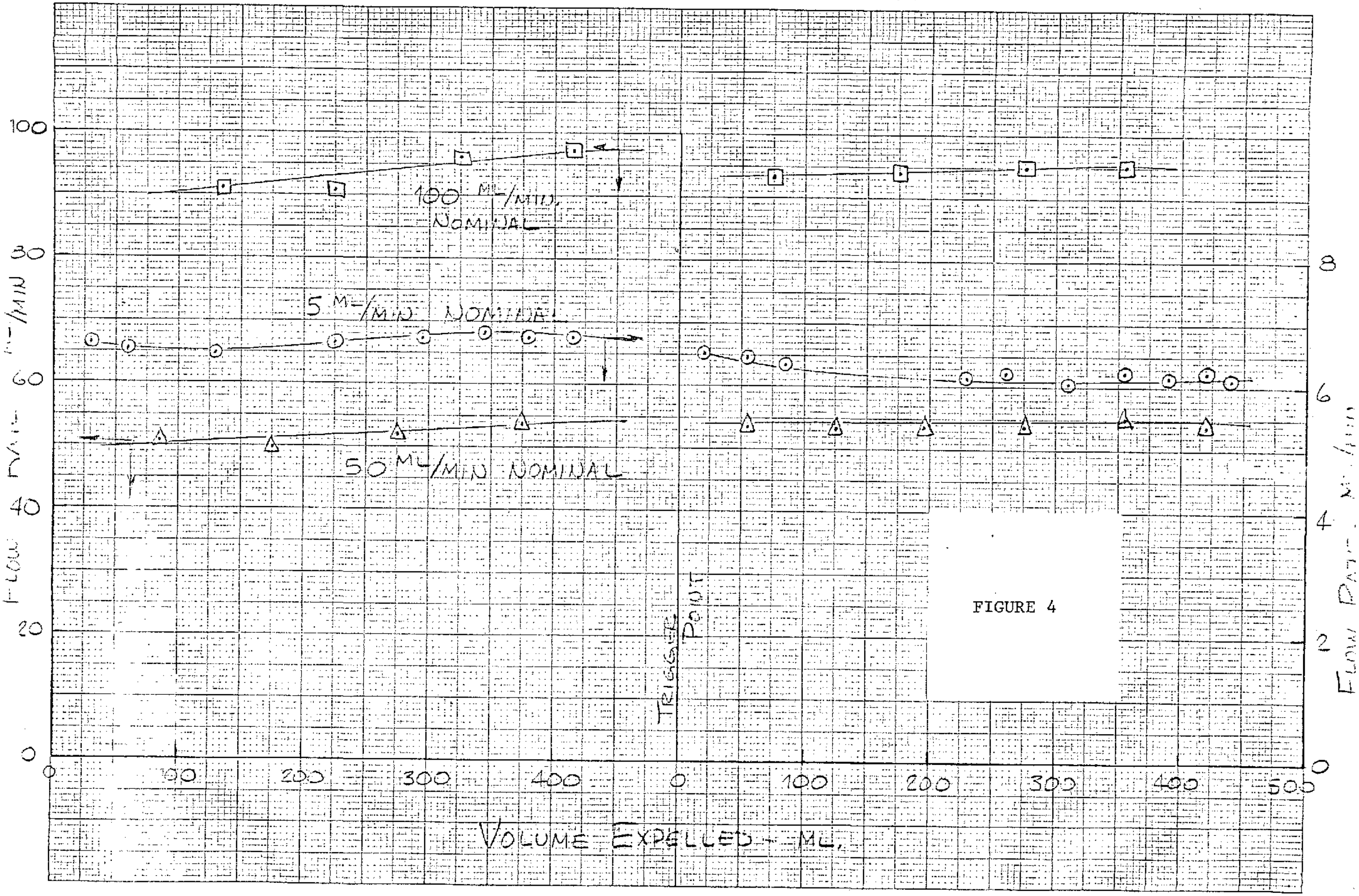

FIGURE 4

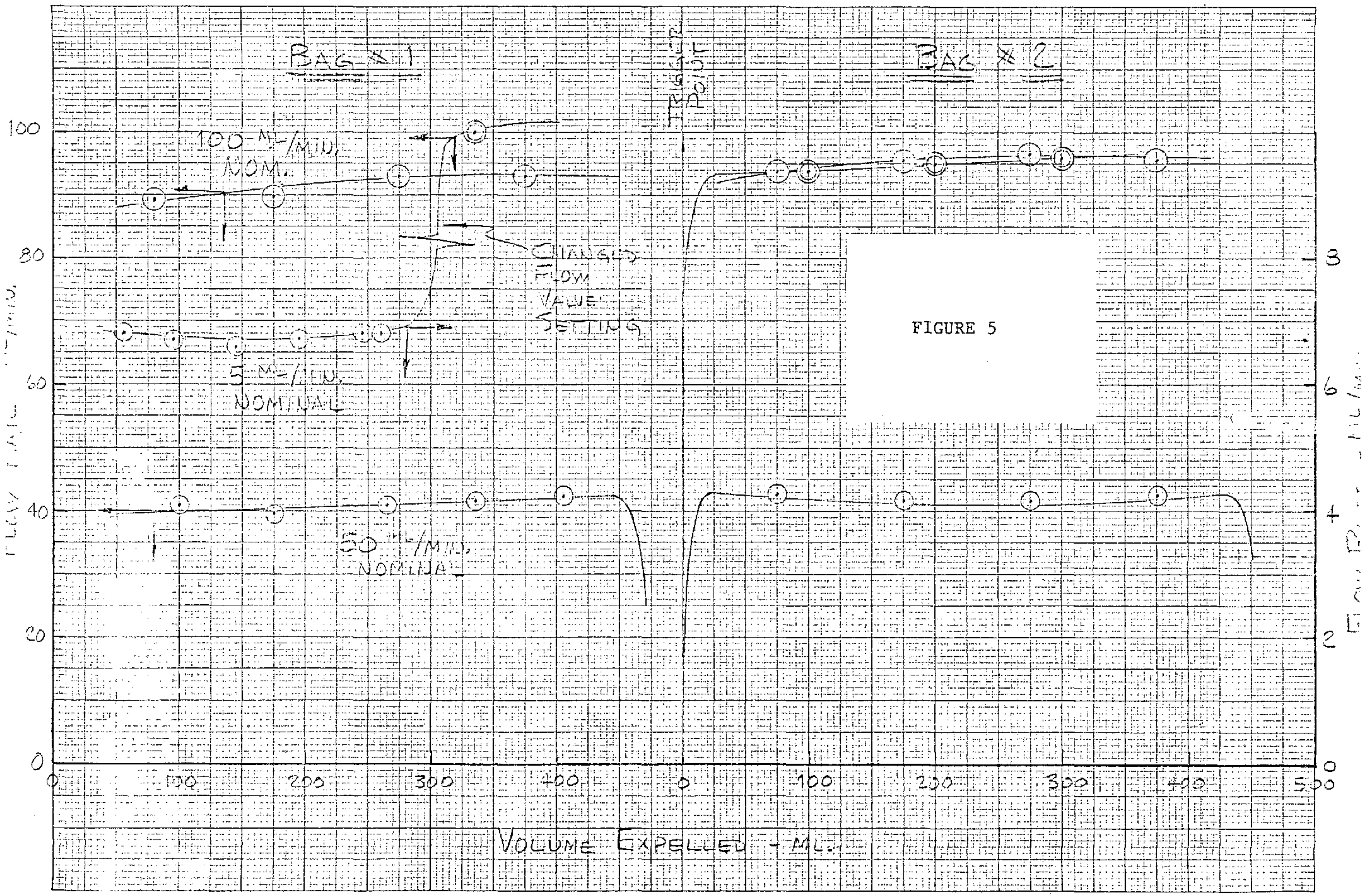

FIGURE 5

IVI PROTOTYPE SYSTEM - ACCEPTANCE TEST 16DEC71

2.2 Bubble Alarm Tests

Tests were conducted to establish the operating threshold of the bubble/no flow alarm on the modified Carolina Medical Electronics blood flowmeter. Air bubbles were injected into the fluid stream through the septum of the drug injection port using a microsyringe. Bubbles of measured size were injected, and a determination made as to the size bubble that would always trip the alarm, and the size that would trip the alarm about 50% of the time. At the higher flow rates, a larger bubble is required for an alarm due to shorter residence time in the flow probe. Results were as follows:

Nominal Flow Rate	Bubble Size for 0.5 Alarm Probability	Bubble Size for 1.0 Alarm Probability
5 ml/min.	.02 ml	.03 ml
50 ml/min.	.08 ml	0.1 ml
100 ml/min.	.20 ml	0.25 ml

2.3 Pneumatic System Performance

The CO_2-powered pneumatic system was proven out in initial operation of the prototype system. No basic problems of gas bottle icing, materials compatibility, etc., were found. The ability of one 25-gram CO_2 bottle to power the system through a useful number of bag evacuations was verified by test. The lower limit on usable CO_2 bottle pressure was found to be 500 psi--i.e., if bottle pressure is not at or above that pressure, a 2-bag run cannot be undertaken with assurance that there will be enough gas in the system to complete the run. The 25-gram bottle was found to consistently supply enough gas for eight complete runs; i.e., to infuse a total of sixteen 500-ml fluid bags.

3.0 ACCEPTANCE TESTING

Acceptance testing of the unit was performed to demonstrate the performance of the system and its suitability for clinical use.

3.1 Flow Tests

Flow tests were repeated using the engineering flow test procedures. The results obtained are shown in Figure 5, and test data sheets are in the

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Appendix. The flow rate was adjusted upward on the low flow run once steady low flow had been demonstrated.

3.2 Animal Testing

Use of the unit in a clinical environment was demonstrated by infusion of 750 ml of normal saline solution into a laboratory animal. The system was operated normally, with complete delivery from the first bag and automatic switching to the second bag. Flow rates over the entire range were selected during the infusion, with the blood flowmeter being used to monitor flow rate. The test was completed successfully.

APPENDIX

ACCEPTANCE TESTING DATA SHEETS

DATE: 16 Dec 74

FLOW TEST DATA SHEET - I.V.I. UNIT

NOMINAL FLOW RATE 100 ML/MIN FLUID 0.9% Saline
BOTTLE PRESSURE: 960 PSI REGULATED PRESSURE: 15 PSI
DELIVERY HEAD: AT TIP 3.5 " H_2O AT BAG TOP 3.5 " H_2O
DELIVERED VOLUME: AT TRIGGERING 445 ML END BAG 2 410 ML

BAG No.	INITIAL VOLUME ML.	FINAL VOLUME ML.	ELAPSED TIME SEC.	METER READING ML/MIN	CALCULATED FLOW ML/MIN	REMARKS
1	55	105	33.8	96	89.3	
	150	200	33.4	100	89.8	
	250	300	32.2	100	93.1	
	350	400	32.2	102	93.1	
2	50	100	31.9	103	93.9	
	150	200	31.4	104	95.6	
	250	300	31.0	106	96.7	
	350	400	31.4	—		
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DATE: 16 Dec 74

FLOW TEST DATA SHEET - I.V.I. UNIT

NOMINAL FLOW RATE 50 ML/MIN FLUID 0.9% Saline

BOTTLE PRESSURE: 950 PSI REGULATED PRESSURE: 15 PSI

DELIVERY HEAD: AT TIP 3.5" H_2O AT BAG TOP 3.5" H_2O

DELIVERED VOLUME: AT TRIGGERING 455 ML END BAG 2 445 ML

BAG No.	INITIAL VOLUME ML.	FINAL VOLUME ML.	ELAPSED TIME SEC.	METER READING ML/MIN	CALCULATED FLOW ML/MIN	REMARKS
1	75	125	73.4	43	41	
	150	200	75.3	43	39.7	
	240	290	73.2	44	41	
	310	360	71.9	45	41.8	
	380	430	70.8	46	42.3	
2	50	100	70.0	47	42.8	
	150	200	71.8	47	41.8	
	250	300	72.0	47	41.7	
	350	400	70.6	48	42.5	
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DATE 16 DEC 74

FLOW TEST DATA SHEET — I.V.I. UNIT

NOMINAL FLOW RATE 5 ML/MIN FLUID 0.9% Saline

BOTTLE PRESSURE: 950 PSI REGULATED PRESSURE: 15 PSI

DELIVERY HEAD: AT TIP 3.5" H_2O AT BAG TOP 8.0" H_2O

DELIVERED VOLUME: AT TRIGGERING 450 ML END BAG 2 415 ML

BAG NO.	INITIAL VOLUME ML	FINAL VOLUME ML	ELAPSED TIME SEC	METER READING ML/MIN	CALCULATED FLOW ML/MIN	REMARKS
1	50	55	44.4	8	6.8	
	90	95	45.0	8	6.7	
	140	145	45.4	9	6.6	
	190	195	45.0	10	6.7	
	240	245	44.3	11	6.8	
	255	260	44.2	12		Ground off
	310	360	30.0	11.6	100	Increased Flow
2	75	125	31.9	11.1	94	
	175	225	31.5	11.1	95.2	
	275	325	31.2	11.2	96	
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